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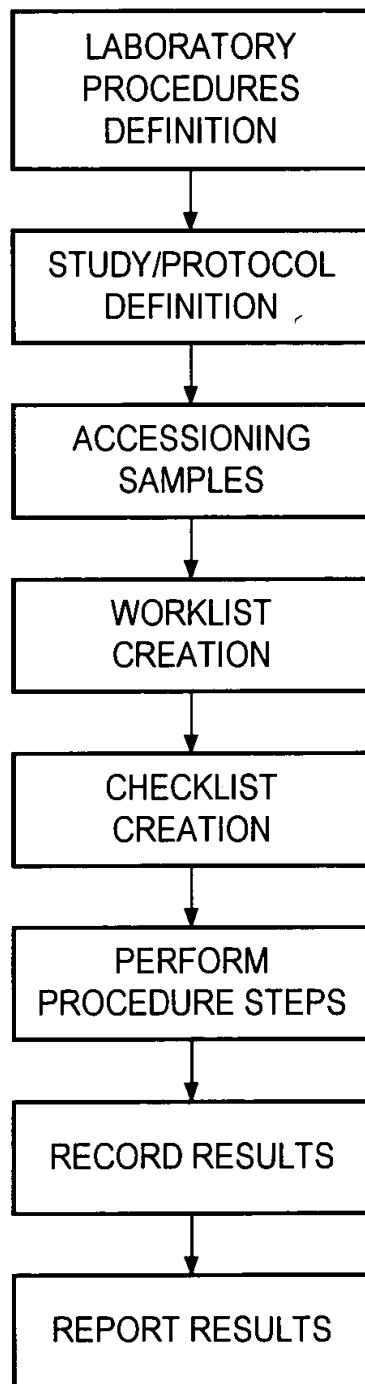
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**FIG. 1**

## Study Setup

### Clinical Study Definition

- Describes Sponsors & Investigators
- Declares Subject Attributes to Capture
- Associates Specific Lab Procedures with a Clinical Study
- Defines Genotype Results to Report

**Study Protocols**

**Sponsor:** A Co., John Doe, Ph.D.  
**Sponsor Representative:** John Doe, Ph.D.  
**Sponsor/Study No:** 198-005  
**Study No:** 632-001

**Investigators:** John Doe, Ph.D.

**Sponsor/Protocol Title:** Pharmacokinetic Evaluation of Oros(R) (oxibutyrin chloride) and IR oxibutyrin Administered Alone and in the Presence of Ketoconazole

**PPG's Protocol Title:** Genomic DNA isolation and molecular genotyping analysis of CYP2D6 "A", "B", "D", "E", "G", and "H" alleles

**Procedures:** DNA Isolation, 3 mL whole blood, Purgene Kit; SpectroMax DNA quantitation; CYP2C9\*3; CYP2C9\*2 Ver. 7

**Subject Attributes:** Subject Number, Gender, Birthdate, Ethnicity

**Final Storage Tube Range (1):**

**Barcode Accession Number:**

**Barcode Length:**

**Buttons:** Define Results, New, Modify, Delete, Save, Cancel, Close

**Created:** 10/4/99 12:02  
**Modified:** 10/5/99 14:38  
**DNALIMS**

Fig. 2

# Accessioning

## Clinical Sample Registration

- Provides Validation Checks for Accession & Tube ID's
- Accommodates Multiple Sample Tubes
- Enforces Controlled Subject Attribute Terms
- Supports Sample Workflow

**Accessioning**

Study No.	Accession No.	Sponsor Sample Tube ID	Sample Tube ID	Received Date	Location
632-001	A100123	BA10112	PS22156	09-OCT-1999	
632-001	A100124	BA10113	PS22157	09-OCT-1999	
632-001	A100125	BA10114	PS22158	09-OCT-1999	
632-001	A100126	BA10115	PS22159	09-OCT-1999	

**PPGx Study No:** 632001 **Sponsor:** A Co. (John Doe, Ph.D.)

**Accession No:** A100126 **Date Received:** 09 Oct 1999 **Sample Type:** Fresh Whole Blood

**Sponsor Sample Tube ID:** BA10115 **Tube 1** **Tube 2 (f)** **Tube 3 (f)** **Tube 4 (f)**

**PPGx Sample Tube ID:** PS22159

**Sample Tube Volume:** >=5 **Sample Condition:** Good

**Comments:**

**Subject Attributes:**

Subject Number	15678
Gender	M
Birthdate	18-Sep-88
Ethnicity	Black

**Created:** DNALINS **Modified:** 10/9/99 20:03

Fig. 3

# Sample Tracking

- ◆ Supports Multiple Container Classes
- ◆ Allows User Defined Container Geometries & Templates
- ◆ Maintains Sample & Container Location
- ◆ Permits Flexible Sample Loading & Rearrangement
- ◆ Tracks and Maintains Container & Sample Ownership

Place Sample

Container ID: RACK\_1

Show

Map

#67 6ROWS = 12COLS

Description: 6x12rack

	1	2	3	4	5	6	7
A	BA328382	BA328383	BA328384	BA328385	BA328386		
B	BA328382B	BA328383B	BA328384B	BA328385B	BA328386B		
C							
D							
E							
F							

1 2 3 4 5 6 7

1 2 3 4 5 6 7

Clear Container

Close

Sample Tube ID:

Assign

Position: A6

Close

Fig. 4

- ## Sample Worklists
- ◆ Named Sample Collections
  - ◆ Assignable to Lab Scientists
  - ◆ Groups Samples for Common Lab Operations
    - Location
    - Check-in/Check-out
    - Lab Procedures

**Worklists**

Worklist Name	Assigned To	Created By	Created On	Mo
FOI005	DNALIMS	DNALIMS	10/5/99 13:54	DN
PS1SAMPLES	DNALIMS	DNALIMS	10/6/99 08:02	DN
TODAYSIGENOTYPING	DNALIMS	DNALIMS	10/6/99 17:47	

Modify Cancel Save Save As... Delete New

Worklist Name: **PS1SAMPLES** Assigned To: **DNALIMS**

**Samples:**

Sample Tube ID	Accession ID	PPEN Study No.	Location
S1	A1	PS1	Fr.1 Comp. Shelf Rack
S2	A2	PS1	Fr.1 Comp. Shelf Rack
S3	A3	PS1	Fr.1 Comp. Shelf Rack
S4	A4	PS1	Fr.1 Comp. Shelf Rack
S5	A5	PS1	Fr.1 Comp. Shelf Rack

Check In Check Out Open Checklist Print Worklist

**CONTAINERS**

☒ # R1

☐ Add Container ☐ Add Sample

Created: **DNALIMS** 10/6/99 08:02 Modified: **DNALIMS** 10/7/99 08:50

Clear Worklist Close

Fig. 5

# Electronic Procedure Checklists

- Automates Laboratory Process Tracking
  - Supports Standard Operating Procedures
  - Maintains Uniform Laboratory Processes
  - Records Chain of Custody
  - Tracks Repeat Operations

Procedure	Created By	Created On	Locked For M	Query
DNA Isolation 3 mL whole blood/Purgene Kit	DNALIMS	10/5/99 13:57	DNALIMS	
GP2092 Ver 6	DNALIMS	10/5/99 14:19		
GP2092 Ver 7	DNALIMS	10/5/99 14:39		
GP2092 Ver 7	DNALIMS	10/5/99 14:40		
GP2093	DNALIMS	10/5/99 14:52	DNALIMS	

NOTES	ALL SAMPLES	BA100100	BA100101	BA
Thaw frozen blood	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
Gently mix sample	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
Transfer 3 mL of blood to Lysis tube	DONE	CA1111	CA1112	CA1112
Add 9 mL of RBC lysis to RBC lysis tube	DONE	CA1111	CA1112	CA1112
Mix and incubate 10 minutes at room temperature	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
Centrifuge 10 minutes at 3000RPM		11009	11009	11009
Pour off supernatant into biohazardous waste	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
Resuspend cell pellet by vortexing	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
Add 2 mL of Cell Lysis Solution	DONE	CA1111	CA1112	CA1112

Created	Locked	New Batch
DNALIMS	DNALIMS	10/5/99 13:57
		10/5/99 19:14

Fig. 6



Procedure	Status	SOP Number	SOP Version
DNA Isolation; 3 mL whole blood, Purgene Kit	APPROVED	GEN9709	C
2D6 Allele "A" Identification	APPROVED	CYP2D6A	A
SpectroMax DNA quantitation	APPROVED	MAX9802	A
CYP2C9*3	APPROVED	CYP2C9-3	A
CYP2C9*2 Ver. 7	APPROVED	CYP2C9-2	A
CYP2C9*2 Ver. 6	APPROVED	CYP2C9-2	A

Procedure Name: 2D6 Allele "A" Identification

Print

Save As...

Procedure Description:  
Laboratory Protocol for Identification of CYP2D6 "A" Allele by RFLP-PCR

Genes: Alleles:

SOP Number: CYP2D6A  
SOP Version: A

Status: APPROVED

New Save  
Modify Cancel  
Delete Close

Created: DNALIMS 10/4/99 12:02  
Modified: DNALIMS 10/5/99 10:59

Fig. 7



**Procedure Steps**

Procedure: DNA Isolation, 3 mL whole blood, Purgene Kit

Step	Step Input Type	Functional Type	Level
1. Thaw frozen blood	CheckBox		Batch
2. Gently mix sample	CheckBox		Batch
3. Transfer 3 mL of blood to lysis tube	Functional	Transfer	Batch
4. Add 9 mL of RBC lysis to RBC lysis tube	Functional	Reagent Addition	Batch
5. Mix and incubate 10 minutes at room temperature	CheckBox		Batch
6. Centrifuge 10 minutes at 3000 RPM	Text		Batch
7. Pour off supernatant into biohazardous waste container	CheckBox		Batch
8. Resuspend cell pellet by vortexing	CheckBox		Batch
9. Add 3 mL of Cell Lysis Solution	Functional	Reagent Addition	Batch
10. Sample can be stored for 18 months at RT in Cell Lysis Solution	Informational		Batch
11. STOP HERE	Informational		Batch

Step: Add 9 mL of RBC lysis to RBC lysis tube

Step Level: ☒ Sample ☐ Batch

☒ Informational ☒ CheckBox ☐ Functional ☐ Text

Reagent Addition:

Volume	9000
To final volume	FALSE
Reagent name	RBC Lysis Sol
Reagent prefix	PL
Volume optional	TRUE
Wave scanning	TRUE
Lock parameters	TRUE

Buttons: Save Sequence, New, Delete, Modify, Save, Cancel, Close

Created: DNALIMS 10/5/99 09:00 Modified: DNALIMS 9/30/99 14:42

## Procedure Steps

- ◆ A Single Step in a Lab Procedure
- ◆ Multiple Types:
  - Transfer
  - Dilution
  - Concentration Adjustment
  - Sample Preparation
- ◆ Highly Customizable
- ◆ Plug-in Architecture to Add New Types
- ◆ Interfaces to Automation

Fig. 8

**Results**

Study Protocol: PS1  
Sponsor: C Co. David Jones  
Investigators:

Accession No: A6 Status: OPEN

Study Protocol	Accession No.	Status
PS1	A3	OPEN
PS1	A4	OPEN
PS1	A5	OPEN
PS1	A6	OPEN
PS1	A7	OPEN
PS1	A8	OPEN
PS1	A9	OPEN

Gene: CYP2C9

Gene	Status	Interpretation	Exclude	Final GT	Entered By	Entered On
CYP2C9	COMPLETE	EXTENSIVE METABOLIZER	<input type="checkbox"/>	wt/A	DNALIMS	10/6/99 6:48

Genotyping: DNA Purification Chain Of Custody

Allele	Result	Batch	Procedure	Created By	Created On	Entered
m2	mt/wt	Batch	CYP2C9 2 Ver. 7	DNALIMS	10/6/99 6:09:48 PM	DNALI
m2	mt/wt	Batch	CYP2C9 2 Ver. 7	DNALIMS	10/6/99 6:09:48 PM	
m2	mt/wt		FINAL RESULT			

Buttons: Modify, Cancel, Save, Close

## Genotype Results

- ◆ Accommodates Values for Multiple Genes, Alleles & Assays
- ◆ Provides Master Review by Accession Number
- ◆ Supports Acceptance & Final Approval by Study Director
- ◆ Imports Results Electronically or Manually

**Fig. 9**

## Auditing

- ◆ Track Changes in Database
  - Study
  - Lab Procedures
  - Sample
  - Results
- ◆ Flexible Audit Reporting
- ◆ Chain of Custody by Accession

Audit Report									
Protocol Audit Trail	Audit ID	Protocol ID	Sponsor	STI	Sponsor Protocol Title	PPGX Study	PPGX Protocol Title	Created	B
STUDY_PROTOCOL									
	885	61	A1A		Evaluation of	STUDY-1		x	DNALIMS
	886	61	A1A		Evaluation of	STUDY-1		x	DNALIMS
	901	61	A1A		Evaluation of	STUDY-1		x	DNALIMS
	951	61	A1A		Evaluation of	STUDY-1			Genomic DNA isolation and DNALIMS
	963	61	A1A		Evaluation of				Genomic DNA isolation and DNALIMS
	957	61	A1A		Evaluation of				Genomic DNA isolation and DNALIMS
	980	61	PHO-001		Evaluation of				Genomic DNA isolation and DNALIMS
	984	61	PHO-001		Evaluation of				Genomic DNA isolation and DNALIMS
	971	61	PHO-001		Evaluation of				Genomic DNA isolation and DNALIMS
	988	61	PHO-001		Evaluation of				Genomic DNA isolation and DNALIMS
	1002	61	PHO-001		Evaluation of				Genomic DNA isolation and DNALIMS
	1003	61	PHO-000		Evaluation of				Genomic DNA isolation and DNALIMS
		61	PHO-001		Evaluation of				Genomic DNA isolation and DNALIMS

Fig. 10

